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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,531	11/28/2000	James F. Young	10271-021-999	7010
20583	7590	06/04/2004	EXAMINER	
JONES DAY			CHEN, STACY BROWN	
222 EAST 41ST ST			ART UNIT	
NEW YORK, NY 10017			PAPER NUMBER	

1648

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,531

Applicant(s)

YOUNG ET AL.

Examiner

Stacy B Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 308 is/are withdrawn from consideration.
- 5) ☒ Claim(s) See Continuation Sheet is/are ~~allowed~~ allowable. *smc 5/24/04*
- 6) ☒ Claim(s) 3,5,180,182,261-263,276,281,283,284 and 287 is/are rejected.
- 7) ☒ Claim(s) 280-287 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date April 21, 2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,3,5,179-184,186,187,189,192,193,195,201,204-212,222-227,231-233,241,242,244,245,250,261-263,276,280-299,303 and 305-308.

Continuation of Disposition of Claims: Claims ^{allowable} ~~allowed~~ are 1,179,181,183,184,186,187,189,192,193,195,201,204-212,222-227,231-233,241,242,244,245,250,288-299,303 and 305-307. *src 5/24/04*

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 21, 2004 has been entered. Claims 1, 3, 5, 179-184, 186, 187, 189, 192, 193, 195, 201, 204-212, 222-227, 231-233, 241, 242, 244, 245, 250, 261-263, 276, 280-299, 303 and 305-308 are pending.

2. The objections to the claims for containing a typo and reciting duplicate sequence combinations are withdrawn in view of Applicant's amendments. The provisional rejection of claim 180 under 35 U.S.C. 101 as claiming the same invention as that of claim 55 of the '415 application is withdrawn in view of Applicant's arguments. Claim 180 is now rejected under the judicially created doctrine of obviousness-type double patenting, see below. The provisional rejection of claims 280-282 and 284-287 as unpatentable over claim 73 of US Application 09/996,288, is withdrawn in view of Applicant's amendment. Claims 3, 180 and 182 are now provisionally rejected under the judicially created doctrine of obviousness-type double patenting, as unpatentable over claims 153-158 of US Application 09/996,288, see below.

3. Upon further consideration, claim 308 contains a sequence that was not elected according to the election/restriction requirement mailed February 20, 2002. Applicant chose SEQ ID Nos : 48, 20, 10, 18, 19, 21, 22 and 6. Claim 308 encompasses an isolated antibody comprising a CDR having an amino acid sequence of SEQ ID NO: 27, which was not elected. Therefore, claim 308 is withdrawn from consideration.

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4. For clarification purposes, all claims are drawn to isolated antibodies having amino acid sequences *comprising* SEQ ID NO: X or *comprising* a CDR. The claims recite “amino acid sequence of SEQ ID NO” or “amino acid sequence of a VH CDR”, for example. According to the use of the phrase “amino acid sequence of SEQ ID NO” and “amino acid sequence of a VH CDR” in the specification, the examiner has interpreted the phrase to be the equivalent of “comprising SEQ ID NO”, as opposed to antibodies having amino acid sequence fragments of SEQ ID NO: X or fragments of a CDR region.

Inventorship

5. Applicant’s submission of a Petition for Correction of Inventorship under C.F.R. § 1.48(a) is acknowledged. Inventor William D. Huse has been added to the inventorship of this application. The Office was unable to locate the Statements of Inventors Being Added for Jeffry D. Watkins and Herren Wu. Applicant is requested to re-submit copies of statements for Jeffry D. Watkins and Herren Wu. All other requirements for Correction of Inventorship under C.F.R. § 1.48(a) have been met.

Information Disclosure Statement

6. The information disclosure statement filed April 21, 2004 has been considered.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claims 3, 5, 281 and 283 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to an antibody comprising a variable light (VL) domain having an amino acid sequence of SEQ ID No: 20, which, unless indicated otherwise, reads on a naturally occurring antibody. Suggested language is “isolated antibody”.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 261-263, 276, 284, 287 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claims 261-263 and 276 depend from cancelled claims.
- Claim 284 recites “a therapeutic or drug moiety”. This is unclear because there is no indication of what these moieties are, nor any associated therapeutic function.
What is the therapeutic/drug moiety treating?
- Claim 287 recites “instructions for use”, which is unclear because the “use” is not identified in the claim.

Double Patenting

9. Claim 180 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 10 of U.S. Patent No. 6,656,467. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to use the antibody of patented claim 10 having SEQ ID NO: 9, which corresponds to SEQ ID NO: 10 of the instant invention. One would have been motivated to use SEQ ID NO: 9 because it is a CDR of an antibody that binds RSV, and the instant claimed antibody is an antibody that binds RSV. The neutralizing activity and affinity constant of the instantly claimed antibody comprising SEQ ID NO: 10 are expected to have the same properties as the antibody of patented claim 10, which comprises the same sequence. Lacking any structural differences, the properties of the antibodies are expected to be the same.

10. Claims 3, 180 and 182 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 153-158 of copending Application No. 09/996,288. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to antibodies comprising SEQ ID NO: 10, 19 and 20, and the conflicting claims are drawn to a composition comprising antibodies having SEQ ID NO: 10, 19 and 20. The conflicting claims are also drawn to a composition of two or more antibodies having SEQ ID NO: 10, 19 and 20. It would have been obvious to have the instantly claimed antibody in a composition, since an antibody is typically stored in a composition to maintain its structure. It would have been obvious to have a

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composition of one or more or two or more species of antibodies in a composition as opposed to a single antibody, since antibodies bind multiple epitopes.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

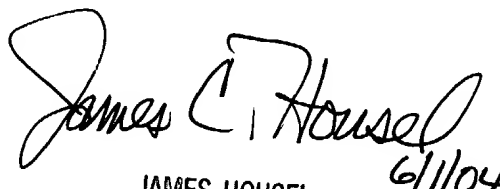
11. Claims 280-287 are objected to for depending from rejected claim 3. The antibody CDR sequences as claimed in their various combinations are free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Stacy B. Chen
May 24, 2004



JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
6/1/04